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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,978	01/22/2004	David Hung	12.024011	5996
38732	7590	10/30/2006	EXAMINER	
CYTYC CORPORATION 250 CAMPUS DRIVE MARLBOROUGH, MA 01752			SZMAL, BRIAN SCOTT	
			ART UNIT	PAPER NUMBER
			3736	

DATE MAILED: 10/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/762,978

Applicant(s)

HUNG ET AL.

Examiner

Brian Szmaj

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 September 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 90-100 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 90-100 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 January 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### ***Drawings***

1. The drawings are objected to because element "110" in Figure 1 does not directed towards the ductal sphincter, and instead points to stop "29". In Figure 10, element "27" should be "26" to conform to Figures 1-3 and 5B. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "28" has been used to designate both the distal tube in Figure 4 and a collection tube in Figures 1-3, 5B and 10. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid

Art Unit: 3736

abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Claim Objections***

3. Claim 90 is objected to because of the following informalities:

In line 1, "said method comprising;" should read as "said method comprising:".

Appropriate correction is required.

4. Claims 96 and 99 are objected to because of the following informalities: Both claims disclose "a collection device", while Claim 90 previously disclosed "a collection device" in line 15 of the claim. It appears that "a collection device" in Claims 96 and 99 should read as either "the collection device" or "said collection device". Appropriate correction is required.

### ***Double Patenting***

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct

Art Unit: 3736

from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 90-100 are rejected on the ground of nonstatutory obviousness-type

double patenting as being unpatentable over claims 62-65 and 68 of U.S. Patent No.

6,689,070 B2. Although the conflicting claims are not identical, they are not patentably

distinct from each other because the claims of the current application and the issued

patent both disclose a method for lavaging a human breast duct, including essentially

the same structural elements and method steps. While the issued patent broadly

discloses the use of a catheter with an internal lumen, the current application discloses

all of the structural elements of the catheter. One of ordinary skill in the art would be

able to determine a catheter would inherently have a proximal end and a distal end and

have an internal lumen with a distal opening for receiving and/or delivering a fluid into

the body. Furthermore, the issued patent broadly discloses an infusion device and a

collection device, while the current claims disclose a syringe for infusing a fluid and a

syringe for collecting the fluid. One of ordinary skill in the art would be able to determine

that an infusion device would inherently be a syringe, while the collection device would

also inherently be a syringe. Since the claims of the issued patent broadly disclose the

limitations of the current claims of the application, the current claims are not patentably distinct from the issued claims.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 90-100 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cecchi (5,843,023) in view of Hou et al (A Simple Method of Duct Cannulation and Localization for Galactography before Excision in Patients with Nipple Discharge).

Cecchi discloses an aspiration needle with a side port and further disclose: a manifold hub (17) in fluid communication with the cannula (13), the manifold hub (17) comprising a distal end having a first port (29) for infusing fluids into the hub (17) and a second port (16) for collecting fluid from within the hub (17); infusing a lavage fluid through the first port (29) and into the hub (17) (See Figures 1 and 2; and Column 5, lines 21-24); infusing lavage fluid from the hub (17) into the target site through the internal lumen (30) of the cannula (13) (See Figures 1 and 2; and Column 5, lines 21-24); withdrawing the lavage fluid and substances borne by the lavage fluid from the target site through the lumen (30) of the cannula (13) and into the hub (17); delivering the lavage fluid into a collection device (26) through the second port (16) of the hub (17) (See Column 3, lines 9-14; and Column 5, lines 21-24); infusing the lavage fluid

Art Unit: 3736

includes the step of applying a positive infusion pressure within the internal lumen (30) (See Column 3, lines 11-14; and Column 5, lines 22-24); the positive pressure is applied by a syringe (See Column 5, lines 22-24; "injecting saline or other media" inherently discloses the use of a syringe); infusing the lavage fluid includes applying a positive pressure within the hub (17) (See Column 5, lines 22-24); withdrawing the lavage fluid and substances includes applying negative pressure within the internal lumen (30) (See Column 5, lines 22-23 and 46-47); the negative pressure is applied by a collection device, which is a syringe (See Column 5, lines 46-47); and withdrawing the lavage fluid and substances includes applying a negative pressure within the hub (17) (See Column 2, lines 62-64; the vacuum source creates a vacuum which is then transmitted to the hub and then to the internal lumen of the cannula in order to aspirate the sample).

Cecchi however fail to disclose inserting a distal end of a catheter through the ductal orifice and into a distal lumen of a duct or ductal network; the catheter comprising a proximal end and a distal end, and an internal lumen extending between the proximal and distal ends, the distal end including an opening for delivering lavage fluid within the duct and receiving fluid from within the duct.

Hou et al disclose a method and means for placing a lavage fluid within a breast duct and receiving fluid from within the duct, and further disclose inserting a distal end of a catheter through the ductal orifice and into a distal lumen of a duct or ductal network; the catheter comprising a proximal end and a distal end, and an internal lumen extending between the proximal and distal ends, the distal end including an opening for

Art Unit: 3736

delivering lavage fluid within the duct and receiving fluid from within the duct. See Paragraph 4, under Materials and Methods, page 568, lines 1-7 and 12-17.

Since both Cecchi and Hou et al disclose means for infusing a lavage fluid and aspirating the lavage fluid and biological material from a target site, it would have been obvious to one of ordinary skill in the art to modify the method of Cecchi to utilize the device for lavaging a breast duct, as per the teachings of Hou et al, since it would provide a means of utilizing a single syringe for creating a vacuum and aspirating a sample and a second syringe for providing a lavage fluid.

### ***Response to Arguments***

9. Applicant's arguments with respect to cancelled claims 79-89 and new claims 90-100 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmaj whose telephone number is (571) 272-4733. The examiner can normally be reached on Monday-Thursday, with Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Art Unit: 3736

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink, appearing to be 'BS' with a stylized flourish.

BS